

## **REMARKS**

The following claims are currently being amended:

- (A) Pending claims: 1 and 18;
- (B) Withdrawn claims: 60 and 72.

The unelected, withdrawn claims are being amended so that they remain commensurate in scope with the elected product claims for later rejoinder.

Applicants acknowledge and thank the Examiner for withdrawing the rejections under 35 U.S.C. §102(b) and U.S.C. §103(a), as noted above.

Applicants discuss the Office's reasons for withdrawal of these rejections as they pertain in part to the amendment of claims 1 and 18 (as well as 72). All the new amendments are supported by the original claims and the specification throughout. No new matter is added by these amendments. Entry and allowance of the amended claims is respectfully requested.

### **I. Withdrawal of § 102(b) Rejection**

The Office withdrew the rejection of claims 1, 3, 4, 18 and 20-26 under 35 U.S.C. 102(b) as anticipated by Caggana. This was based at least in part by the Examiner's appreciation of the differences between "replacement" and "insertion" vector technology as explained in the prior Response and the Declaration. Applicant Ramsingh distinguished the instant claims from the cited Caggana reference by showing that Caggana's vector used replacement technology, while the instant claims use insertion technology. The only caveat noted by the Office was that Claims 1 and 3 did not recite an "insertion" limitation, as did claim 4 and claims dependent thereon. This has been done by the present amendment, as discussed below.

### **II. Withdrawal of § 103 (a) Rejection**

The Office withdrew the rejection of claims 1, 3-6, 13-15, 17, 18 20-23 and 28 as obvious over Tracy in view of Applicant's arguments and the second declaration of Arlene I. Ramsingh filed 27-FEB-04. The Office acknowledged the differences between Tracy's vector, which does not disclose a heterologous polypeptide fused to a capsid protein of the virion. Further, the Office Action stated that:

[i]n response to Applicant's argument regarding the fusion aspect of Applicant's invention, now recited in claim 1, the Office recognizes the distinction between Tracy and the instant invention.

Thus, the Office considers all pending claims to be free of the Tracy reference and unobvious.

### III. NEW REJECTION UNDER 35 U.S.C. § 112, first paragraph

Claims 1, 3, 4, 6-15, 17-18, 20-28 and 30-36 have been newly rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, as briefly noted above. The claims were alleged to include subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection was based on the introduction into claim 1 and, thereby, to all its dependent claims, the limitation of "non-coxsackievirus." The Office maintained that this language is not supported by the specification, which Applicants understand to mean that the Office considers a "heterologous non-coxsackievirus nucleic acid to be an "undisclosed subgenus" (or negative limitation) of heterologous nucleic acids.

While the law concerning such subgenres and their addition during prosecution is complex, there is precedent supporting such additions. Noteworthy is the fact that **the Office did not cite any precedent** supporting its position. It merely stated its position as if it were a fact. The Office is known to have relied in the past on the Board's opinion in *Ex parte Grasselli*, 231 USPQ 393 (Pat. Bd. App. & Inf. 1983), on request for rehearing, 231 USPQ 395 (Pat. Bd. App. & Inf. 1983), *aff'd*, 738 F.2d 453 (Fed. Cir. 1984) (unpublished) for its position on "negative limitations" resulting in "undisclosed subgenres". The facts, issues and reasoning in *Grasselli* do not apply to the present claims. The *Grasselli* Board took the position that the negative limitations recited in the claims (...catalyst in the **absence of** sulfur and halogen... said catalyst being **free of** uranium and the combination of vanadium and phosphorus), because they did not appear in the specification as filed, introduced new **concepts** thereby violating the description requirement of 35 U.S.C. § 112, first paragraph (*Grasselli* at 394). The Board added that

the express exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitations do, in fact, introduce new concepts.

*Grasselli* at 394.

For the Office to argue that the limitation “non-coxsackievirus” was not supported is a classic elevation of “form over substance,” an action frowned upon by the Federal Circuit (and Supreme Court) in multiple interpretational contexts almost too numerous to cite and directed to a range of issues from claim interpretation and prosecution history estoppel (*e.g.*, *Deering Precision Instruments, L.L.C. v. Vector Distribution Systems, Inc.*, 347 F.3d 1314 (Fed. Cir. 2003)), to existence of offers for sale (*e.g.*, *3D Systems, Inc. v. Aarotech Laboratories, Inc.*, 160 F.3d 1373 (Fed. Cir. 1998), to analyzing claim steps for being mere algorithms (*In re Schrader* 22 F.3d 290, 30 USPQ2d 1455 (Fed. Cir. 1994). See also the U.S. Supreme Court in *Parker v. Flook* 437 U.S. 584 (1978)).

Since the *Grasselli* decision, the Board of Patent Appeals and Interferences has described the legal standard and PTO burden for rejecting a claim due to lack of adequate descriptive support:

**...it is incumbent upon the examiner to establish that the originally-filed disclosure would not have reasonably conveyed to one having ordinary skill in the art that an appellant had possession of the now claimed subject matter.** *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 U.S.P.Q.2d 1767 (Fed. Cir. 1993). Adequate description under the first paragraph of 35 U.S.C. 112 **does not require literal support for the claimed invention.** *In re Herschler*, 591 F.2d 693, 200 U.S.P.Q.; 711 (CCPA 1979); *In re Edwards*, 568 F.2d 1349, 196 U.S.P.Q. 465 (CCPA 1978); *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (CCPA 1976).

*Ex Parte Parks*, 30 USPQ2d 1234 (Bd. Pat. App. & Inter. 1993) (emphasis added).

In making the present rejection, the Office has not met this burden. Applicants wish to state for the record that the present claims are **not** an example of a negative limitation leading to a “new concept” as set forth in *Grasselli*. In fact, as the present Office Action points out explicitly, “the specification gives examples of epitopes of interest that are non- coxsackievirus (page 19)”. Not only that, all the *Examples* are directed to such heterologous products (Example 1: ovalbumin peptides; Example 2: HIV gag p24 peptides; Example 3: HIV peptides). That alone is adequate support for a claim directed to viruses with inserted heterologous DNA that is not “non-coxsackie.”

Thus, Applicants believe that their previous claims as submitted 27-FEB-04 do not run afoul of 35 U.S.C. § 112, first paragraph, which was improperly applied by the Office, while the claims fully overcame all prior art rejections as documented by the Office’s conclusions.

However, because the rejection in the present Office Action is final, and because the earlier Examiner has been replaced by a new one, sowing further complexity in the prosecution of this case, Applicants have decided to do their utmost to simplify issues at this point and to amend the claims

by removing references to “non-coxsackievirus.” Thus, as noted in the Office Action, Applicants emphasize the novelty (and unobviousness) of the “insertion” of heterologous nucleic acids into the coxsackievirus genome (as opposed to the “replacement” of sequences in the cited art), and the fusion of the encoded heterologous polypeptide to a virion capsid protein. Applicants cite the Examiner’s own words:

Points 5 and 6 discuss the differences between “replacement” and “insertion” vector technology. Ramsingh distinguishes the instant claims from the Caggana reference by showing that Caggana’s vector used replacement technology, while the instant claims use insertion technology. In response, Claims 1 and 3 do not recite any limitation about insertion, as in claim 4, for example.

With the present, amendments, claims 1 and 3 now do recite the “insertion” language:

...heterologous nucleic acid inserted within the open reading frame of its genome  
which inserted nucleic acid encodes...

Similarly, claim 18 now recites:

...a heterologous nucleic acid insert which is inserted within the open reading frame  
of its genome, wherein the insert encodes a heterologous polypeptide...

Note also that the withdrawn claims have been amended in a similar manner by virtue of their dependence from the pending composition claims, and the explicit amendment of claim 72.

The “non-coxsackievirus” language following the word “heterologous,” introduced in the paper of 27-FEB-04, has been deleted in all instances (without prejudice to the Applicants seeking claims with such language in a continuation application, based on reasoning such as that provided by Applicants above and the Office’s patently erroneous § 112 rejection).

Having made clear that the heterologous nucleic acid is “**inserted**” into the viral genome, Applicants have complied with the Office’s conclusion that this language is sufficient to overcome the cited art without touching any overly sensitized “written description” nerves. In view of these amendments, there is no remaining basis for the pending rejection, and it should be withdrawn.

#### IV. Miscellaneous Amendment

Claim 60 is amended to remove an extraneous occurrence of the word “virion” that Applicants believe inadvertantly was added to that claim in the paper of 27-FEB-04.

**V. Conclusion**

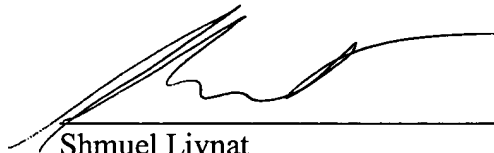
In conclusion, it is respectfully requested that the above amendments, remarks and requests be considered and entered. Applicant respectfully submits that these amendments have simplified issues after final, and that all the present claims are therefore in condition for allowance. It would further be proper to rejoin claims 54-72 at this time. Applicants respectfully request early notice of such favorable actions.

**Examiner Chen is respectfully requested to contact the undersigned at (202) 496-7845 with any questions or comments if this will assist in understanding this amendment and response.**

In the unlikely event that the Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due to **Deposit Account 50-0911**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: **03 December2004**

  
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<sup>1</sup> Again, the Office is respectfully requested to note change in correspondence address.